

Karen I. Boyd (SBN 189808)
boyd@turnerboyd.com
Jennifer Seraphine (SBN 245463)
seraphine@turnerboyd.com
Keeley I. Vega (SBN 259928)
vega@turnerboyd.com
Joshua Rayes (SBN 316208)
rayes@turnerboyd.com
TURNER BOYD LLP
702 Marshall Street, Suite 640
Redwood City, CA 94063
Telephone: 650.521.5930
Facsimile: 650.521.5931

Attorneys for Plaintiff
ALIGN TECHNOLOGY, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ALIGN TECHNOLOGY, INC.,

Plaintiff,

v.

STRAUSS DIAMOND INSTRUMENTS, INC.,

Defendant.

) Case No. 3:18-cv-06663-TSH

) **DECLARATION OF AVI KOPELMAN IN**
) **SUPPORT OF PLAINTIFF'S MOTION FOR**
) **PRELIMINARY INJUNCTION**

REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED

1 I, Avi Kopelman, declare as follows:

2 1. I am Vice President and Chief Scientist of Align Technology, Inc. (“Align”). I have
3 personal knowledge of the statements below, and if called upon in Court to testify would testify as
4 follows.

5 2. In my roles as Vice President and Chief Scientist, I work in the RD group out of the San
6 Jose, California office. I work with multiple research and development people, where we develop
7 innovative orthodontic appliances scanners and related scanner wands.

8 3. I have worked at Align for 8 years, and previously at Cadent with similar technology since
9 1994. I am familiar with Align’s business, reputation, and products.

10 4. One of Align’s products is the well-known Invisalign system. Align’s Invisalign system is
11 a proprietary method for treating malocclusion with a series of doctor-prescribed, custom-
12 manufactured, clear plastic, removable aligners. The system—sometimes called clear braces—
13 straighten teeth using clear, removable, plastic trays.

14 5. Align also developed, makes and sells the iTero Element scanner. There are currently
15 three models of Align’s iTero intraoral scanner offered by sale by Align: the iTero Element, the iTero
16 Element 2, and the iTero Element Flex (collectively the “iTero Element scanner”).

17 6. I am very familiar with the development and operation of Align’s iTero Element intraoral
18 scanner. I was a member of the team that wrote the specification for the scanner and a member of the
19 group that developed it.

20 7. The iTero Element scanner is a handheld intraoral scanner system that is used to take three
21 dimensional scans of a patient’s mouth, teeth, and gums. These scans are used in preparing the trays for
22 the Invisalign system, and also for other dental and orthodontic procedures, such as veneers, inlays,
23 onlays, crowns, bridges and implant abutments; digital records storage; orthodontic diagnosis; and
24 orthodontic retainers and appliances.

25 8. The digital images produced by the iTero Element scanner are a major improvement over
26 the prior methods of taking physical analog impressions that can be messy and uncomfortable for
27 patients. The 3D scans created by the iTero Element scanner are more efficient, more precise, and
28 more comfortable for patients.

1 9. The digital scans also substantially reduce the rate of restoration “remakes” so that patients
2 are recalled less often.

3 10. Also, the appointment time for the digital scan is shorter because of fewer adjustments,
4 which results in greater overall patient satisfaction.

5 11. The iTero Element scanner includes a computer system with an attached “wand,” which
6 collects thousands of images per second as dental practitioners use it to scan a patient’s mouth.

7 12. The proprietary software of the iTero Element scanner then produces a precise, high-
8 resolution, color 3D model of the patient teeth and gums.

9 13. The iTero Element scanner includes a protective sleeve
10 (shown at right), which slides over and covers the portion of the scanning
11 wand that is inserted into the patient’s mouth.



12 14. Align’s sleeve is disposable and single-use only, which among other things protects
13 patients from cross-contamination.

14 15. The iTero Element sleeve includes a window opening having a piece of glass with anti-
15 reflective coating, among other specialized coatings, to optimize the quality of the 3D scan. The sleeve
16 and this window incorporate a proprietary design developed to ensure that scans with the iTero Element
17 scanner have the accuracy and quality that Align advertises and doctors require.

18 16. In the iTero Element sleeve, the glass window is secured in place with a bracket. In use,
19 the sleeve “clicks” into place over the wand, indicating to the user that the sleeve is in place, and
20 ensuring a secure and safe fit and grip. This correct positioning also ensures a precise scan.

21 17. A lower or inferior quality sleeve may, and likely will, reflect not only on the sleeve
22 quality, but also on the performance of the iTero Element scanner system as a whole, and may also
23 increase risk to patients in cross-contamination, fluid transfer, and also discomfort and inconvenience.

24 18. Align learned about Strauss Diamond’s MagicSleeve product in or around September
25 2018. At that time, I contacted Arye Shahar at Strauss Diamond, to request that Strauss Diamond stop
26 selling its product, including stopping using Align’s trademarks. Mr. Shahar refused to do so, but
27 offered to stop if Align would pay Strauss Diamond.
28

1 19. I have seen the MagicSleeve product and evaluated with help of other Align people the
2 product's quality, including as used on the iTero Element scanner.

3 20. I understand that unlike the iTero disposable scanner sleeve, the MagicSleeve is marketed
4 as "reusable." Reusing the sleeve, which covers the portion of the iTero Element system wand inserted
5 into a patient's mouth, increases the likelihood of cross-contamination between patients. Without
6 proper and careful sterilization between each use, the risk of cross-contamination between patients is
7 high.

8 21. Also, unlike the bracket in Align's iTero scanner sleeve, there is no mechanism to connect
9 the loose window to the MagicSleeve. Because the MagicSleeve is not sealed at all, fluids may leak
10 inside and wet the wand, again increasing the risk of cross-contamination between patients.

11 22. This may also occur if the scan is performed without the separate glass window piece.

12 23. The lack of a secure connection between the removable window and the sleeve in
13 Defendant's product also increases the likelihood that the window will be in an incorrect position and
14 result in a poor scan.

15 24. The absence of any mechanism to secure the glass in the MagicSleeve increases the
16 chances that there will be no physical contact between the glass window and the corresponding glass on
17 the wand, which is necessary to ensure the thermal connection between the two required for an effective
18 scan.

19 25. Also, during assembly, because the glass may, and likely will, need to be adjusted to fit,
20 the MagicSleeve glass may become dirty, or acquire fingerprints or other contamination that may
21 distort the scan and cause image capture issues during scanning.

22 26. Also, the window in the MagicSleeve does not have an anti-reflective coating and is
23 thicker than the glass with which the iTero Element scanner is calibrated.

24 27. These differences result in lower view finder and poor 3D scan quality when the iTero
25 Element scanner is used with the MagicSleeve, as compared to when it is used with Align's iTero
26 Element scanner sleeve.

1 28. Also, because the sleeve also covers the wand, the lack of attachment of the window in the
2 MagicSleeve increases the risk of damage to the wand itself, which also has a glass portion over the
3 scanning mechanism.

4 29. Because the MagicSleeve must be autoclaved after each use and includes a removable
5 glass window that must be inserted prior to use, using it also increases the time required to perform a
6 scan.

7 30. For these reasons, and others, Align has not validated the compatibility and use of the
8 MagicSleeve product with the iTero Element scanner.

9 31. There are currently over 150,000 Invisalign-trained doctors worldwide.

10 32. As of December 2018, the number of patients treated with the Invisalign system reached
11 six million.

12 33. Align introduced the first iTero Element scanner in 2015, since which time Align's iTero
13 Element scanner has performed over 6.3 million orthodontic scans worldwide, and another three million
14 Invisalign treatment scans.

15 34. Align has invested a tremendous amount of time and resources—technical research and
16 development and design resources—to develop its cutting-edge technology and to promote its branded
17 products.

18 35. Align has also invested hundreds of millions of dollars in product marketing; advertising,
19 including media advertising; sales force compensation; marketing personnel-related costs; and clinical
20 education.

21 36. With respect to the iTero Element scanner specifically: in 2017, Align spent [REDACTED]
22 [REDACTED] in advertising and marketing; and in 2018, that number increased to [REDACTED]

23 37. These significant investments, and Align's high-quality standards, have resulted in
24 considerable customer goodwill and a superior reputation in the industry.

25 38. Align has never authorized or approved Strauss Diamond's use of Align's name, images or
26 trademarks, nor has Align sponsored or endorsed Strauss Diamond's MagicSleeve.

